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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,861	11/14/2003	Jonathan Minden	94363CIPDIVDIV	1855

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

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04/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,861	MINDEN ET AL.	
	Examiner	Art Unit	
	LISA V. COOK	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *23-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the Office Action mailed 24 September 2007 is acknowledged (Paper filed 12/20/07). Claims 1-37 are subject to Restriction and Election Requirement. Claims 23-37 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as claims drawn to a non-elected invention. Claims 1-22 are under consideration.

2. Objections and/or rejections of record not reiterated herein have been withdrawn.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the Examiner on form PTO-892 or Applicant on form PTO-1449 has cited the references they have not been considered. (For example, see listing of references).

4. The information disclosure statement (IDS) filed on 6/22/07 has been considered as to the merits.

Remarks

5. The following application has been reconsidered. It is noted that various related US Patents have been issued. Because the instant claims were not restricted subject matter in the parent applications, the claims have been rejected under obvious double patenting herein. Applicant is invited to show support in order to remove the ODP rejections. See MPEP 804. The instant application claims priority to the following applications:

A. Application number 10/137,180 wherein all the claims are directed to products of a matched set of luminescent dyes.

B. Application number 09/370,743 now US Patent #6,426,190 - wherein the claims were restricted between methods involving net charge, PH and ionic characteristics; methods not comprising net charge; and kits.

C. Application number 08/425,480 now US Patent #6,127,134 – wherein no restriction requirement was imposed.

NEW GROUNDS OF REJECTIONS

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.

A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-5, 13-15 and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,127,134 in view of JP5322770 – Machine English Translation.

The claims of US Patent No. 6,127,134 are directed to methods of evaluating protein compositions in two different cell samples with a matched set of luminescent dyes.

However, US Patent No. 6,127,134 differs from the instant invention in not specifically teaching that the luminescent detection is conducted by capturing images of the dye-labeled proteins at different wavelengths (see instant claim 1 step f and instant claim 13 step f).

JP5322770 teaches procedures to detect and/or compare proteins, nucleic acids, or DNA quickly via electrophoresis. See section 0001. The signals pass along the filters, enter a photomultiplier tube which is a detector and the images are processed. See section 0010. JP5322770 employs multiple filters which are turned to synchronize it with the signal being measured. This technique allowed for separating and measuring of each wavelength in two or more markers. Thus electrophoresis can be simultaneously performed on the same gel and comparison identification can be carried out for each sample. See section 0006. Comparison identification is possible in high precision, without receiving distorted influence of the position of the spot of electrophoresis. Section 0011.

It would have been prima facie obvious to one of ordinary skill in the art to utilize the multiple wavelength detection procedure taught by JP5322770 in the matched luminescent dye procedures of US Patent No. 6,127,134 because JP5322770 taught that this procedure allowed for the detection and/or comparison of proteins, nucleic acids, or DNA quickly via electrophoresis. See section 0001. JP5322770 employs multiple filters which are turned to synchronize it with the signal being measured. This technique allowed for separating and measuring of each wavelength in two or more markers. Thus electrophoresis can be simultaneously performed on the same gel and comparison identification can be carried out for each sample. See section 0006. Comparison identification is possible in high precision, without receiving distorted influence of the position of the spot of electrophoresis. Section 0011.

One of ordinary skill in the art would have been motivated to do this to reduce time and reagents and process one gel instead of two.

8. Claims 1-5, 13-15 and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No. 6,426,190 B1 in view of JP5322770 – Machine English Translation.

The claims of US Patent No. 6,426,190 B1 are directed to methods of evaluating protein compositions in two different cell samples with a matched set of luminescent dyes.

However, US Patent No. 6,426,190 B1 differs from the instant invention in not specifically teaching that the luminescent detection is conducted by capturing images of the dye-labeled proteins at different wavelengths (see instant claim 1 step f and instant claim 13 step f).

JP5322770 teaches procedures to detect and/or compare proteins, nucleic acids, or DNA quickly via electrophoresis. See section 0001. The signals pass along the filters, enter a photomultiplier tube which is a detector and the images are processed. See section 0010. JP5322770 employs multiple filters which are turned to synchronize it with the signal being measured. This technique allowed for separating and measuring of each wavelength in two or more markers. Thus electrophoresis can be simultaneously performed on the same gel and comparison identification can be carried out for each sample. See section 0006. Comparison identification is possible in high precision, without receiving distorted influence of the position of the spot of electrophoresis. Section 0011.

It would have been prima facie obvious to one of ordinary skill in the art to utilize the multiple wavelength detection procedure taught by JP5322770 in the matched luminescent dye procedures of US Patent No. 6,426,190 B1 because JP5322770 taught that this procedure allowed for the detection and/or comparison of proteins, nucleic acids, or DNA quickly via electrophoresis. See section 0001. JP5322770 employs multiple filters which are turned to synchronize it with the signal being measured. This technique allowed for separating and measuring of each wavelength in two or more markers. Thus electrophoresis can be simultaneously performed on the same gel and comparison identification can be carried out for each sample. See section 0006. Comparison identification is possible in high precision, without receiving distorted influence of the position of the spot of electrophoresis. Section 0011.

One of ordinary skill in the art would have been motivated to do this to reduce time and reagents and process one gel instead of two.

9. Claims 6 and 16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,127,134 in view of JP5322770 – Machine English Translation or over claims 1-39 of U.S. Patent No. 6,426,190 B1 in view of JP5322770 – Machine English Translation and further in view of Potter (Electrophoresis, 1990, Vol.11, pages 415-419).

Please see the rejections over claims 1-18 of U.S. Patent No. 6,127,134 in view of JP5322770 – Machine English Translation or over claims 1-39 of U.S. Patent No. 6,426,190 B1 in view of JP5322770 – Machine English Translation as set forth *a priori*.

Claims 1-18 of U.S. Patent No. 6,127,134 in view of JP5322770 – Machine English Translation *or* claims 1-39 of U.S. Patent No. 6,426,190 B1 in view of JP5322770 – Machine English Translation differ from the instant invention in not teaching image processing with arithmetic operations and pixel measurments.

However, Potter discloses a CLIP image processing system for the complete analysis of two-dimensional gel electrophoresis images. The CLIP series computers use a processor for every pixel of the camera image so that image processing algorithms run in parallel. The advantage of the CLIP system is it's speed of processing. See abstract and pages 416-417, for example.

It would have been prima facie obvious to one of ordinary skill in the art to utilize image processing with arithmetic operations and pixel measurments (such as CLIP) as taught by Potter in the claims 1-18 of U.S. Patent No. 6,127,134 in view of JP5322770 – Machine English Translation or over claims 1-39 of U.S. Patent No. 6,426,190 B1 in view of JP5322770 – Machine English Translation because Potter taught that the advantage of the CLIP system is it's speed of processing. See abstract and pages 416-417, for example. In other words, one of ordinary skill would have utilized the CLIP system to obtain results quickly.

10. Claims 7-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,127,134 in view of JP5322770 – Machine English Translation or over claims 1-39 of U.S. Patent No. 6,426,190 B1 in view of JP5322770 – Machine English Translation and further in view of Anderson et al. (Clinical Chemistry, 1981, Vol.27, No.11, pages 1807-1820).

Please see the rejections over claims 1-18 of U.S. Patent No. 6,127,134 in view of JP5322770 – Machine English Translation or over claims 1-39 of U.S. Patent No. 6,426,190 B1 in view of JP5322770 – Machine English Translation as set forth above.

Claims 1-18 of U.S. Patent No. 6,127,134 in view of JP5322770 – Machine English Translation *or* claims 1-39 of U.S. Patent No. 6,426,190 B1 in view of JP5322770 – Machine English Translation differ from the instant invention in not specifically teaching image normalization, substration and multiplication in order to analyze two-dimensional gels.

However, Anderson et al. disclose computerized procedures to evaluate two-dimensional gels. The system comprises programs for image acquisition, background subtracting and smooting (normalizing), spot detection, gaussian spot modeling (multiplying), and pattern matching/comparison. See abstract and pages 1810 –1814. Anderson et al. taught that systematic errors exist in gel analyses due to film variation, densitometric noise, and gel varaiation. See page 1815 last line of column 1 through 1st paragraph of column 2.

Anderson et al. also taught that there are various approaches to the anlaysis of two-dimensional gel images. The choice of a particular procedure of analysis depends on the computer and display hardware available, the qulaity of the patterns to be analyzed, and the mathematical or programming strategy preferred. See page 1808-2nd paragraph. The combination of procedures taught by Anderson et al. to analyze gels allowed for the study of gene expression against the background of the real complexity of the cell. See page 1819 – 2nd column, last paragraph.

It would have been prima facie obvious to one of ordinary skill in the art to utilize gel image processing that included normalization, substration and multiplication as taught by Anderson et al. in claims 1-18 of U.S. Patent No. 6,127,134 in view of JP5322770 – Machine English Translation *or* claims 1-39 of U.S. Patent No. 6,426,190 B1 in view of JP5322770 – Machine English Translation because Anderson et al. taught that his combination of procedures allowed for the study of gene expression against the background of the real complexity of the cell. See page 1819 – 2nd column, last paragraph.

Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ various known gel analyses techniques as a means of optimizing the data, since it has been held that the provision of adjustablity, where needed, involves only routine skill in the art. *In re Stevens,* 101 USPQ 284 (CCPA 1954).

11. Claims 17-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,127,134 in view of JP5322770 – Machine English Translation and further in view of Potter (Electrophoresis, 1990, Vol.11, pages 415-419) or over claims 1-39 of U.S. Patent No. 6,426,190 B1 in view of JP5322770 – Machine English Translation in view of Potter (Electrophoresis, 1990, Vol.11, pages 415-419) as applied to claims 6 and 16 above, and further in view of Anderson et al. (Clinical Chemistry, 1981, Vol.27, No.11, pages 1807-1820).

Please see rejection of claims 1-18 of U.S. Patent No. 6,127,134 in view of JP5322770 – Machine English Translation and further in view of Potter *or* claims 1-39 of U.S. Patent No. 6,426,190 B1 in view of JP5322770 – Machine English Translation in view of Potter as set forth above.

The rejection of claims 1-18 of U.S. Patent No. 6,127,134 in view of JP5322770 – Machine English Translation and further in view of Potter *or* claims 1-39 of U.S. Patent No. 6,426,190 B1 in view of JP5322770 – Machine English Translation in view of Potter differ from the instant invention in not specifically teaching image normalization, substration and multiplication in order to analyze two-dimensional gels.

However, Anderson et al. disclose computerized procedures to evaluate two-dimensional gels. The system comprises programs for image acquisition, background subtracting and smooting (normalizing), spot detection, gaussian spot modeling (multiplying), and pattern matching/comparison. See abstract and pages 1810 –1814.

Anderson et al. taught that systematic errors exist in gel analyses due to film variation, densitometric noise, and gel varaiation. See page 1815 last line of column 1 through 1st paragraph of column 2.

Anderson et al. also taught that there are various approaches to the anlaysis of two-dimensional gel images. The choice of a particular procedure of analysis depends on the computer and display hardware available, the qulaity of the patterns to be analyzed, and the mathematical or programming strategy preferred. See page 1808-2nd paragraph.

The combination of procedures taught by Anderson et al. to analyze gels allowed for the study of gene expression against the background of the real complexity of the cell. See page 1819 – 2nd column, last paragraph.

It would have been prima facie obvious to one of ordinary skill in the art to utilize gel image processing that included normalization, substration and multiplication as taught by Anderson et al. in the method of claims 1-18 of U.S. Patent No. 6,127,134 in view of JP5322770 – Machine English Translation and further in view of Potter *or* claims 1-39 of U.S. Patent No. 6,426,190 B1 in view of JP5322770 – Machine English Translation in view of Potter because Anderson et al. taught that his combination of procedures allowed for the study of gene expression against the background of the real complexity of the cell. See page 1819 – 2nd column, last paragraph.

Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ various known gel analyses techniques as a means of optimizing the data, since it has been held that the provision of adjustablity, where needed, involves only routine skill in the art. *In re Stevens,* 101 USPQ 284 (CCPA 1954).

Response to Arguments

Applicant's arguments against the cited art were considered and found persuasive. The rejections have been withdrawn. The arguments are MOOT.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to methods of identifying protein compositions in two different samples. The samples are labeled with a matched set of luminescent dyes that are required to have certain functions (net charge, ionic characteristics, and pH characteristics) for operability in the claimed procedure. However, the disclosure only sets forth the combination of Cy3 and Cy5 (see examples in the specification).

The matched dye combinations described merely by their functional characteristics (see claims 1 and 13) reads on an infinite number of dye compositions that are not possessed by Applicant. In addition, the vast unknown structures are further not known to be operable in combination for the method instantly claimed. The dyes would have to function together without interference, they would have to emit different wavelengths for differential measurements, they would need to bind the proteins or interest, and migrate appropriately in the electrophoresis procedures. These specifics have only been identified for the dye combination of Cy3 and Cy5.

Accordingly, one of ordinary skill in the art would conclude that the applicant would not have been in possession of the claimed method with any and all dye combinations meeting the claimed functional requirements. Absent evidence to the contrary the experimentation in undue. The desired activity/characteristics of the dyes required to practice the method is not adequately described and was not known in the art.

13. For reasons aforementioned, no claims are allowed.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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571-272-0816
4/11/08

/Lisa V. Cook/
Examiner, Art Unit 1641